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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,574	12/03/2003	Gudmundur Fertram Sigurjonsson	SIGU3011/JEK/JJC	5131

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BACON & THOMAS, PLLC
625 SLATERS LANE
FOURTH FLOOR
ALEXANDRIA, VA 22314

EXAMINER

HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/725,574

Applicant(s)

SIGURJONSSON ET AL.

Examiner

Melanie J. Hand

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-12 and 14-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-12 and 14-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/5/06, 5/11/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-6, 8-12 and 14-23 have been considered but are moot in view of the new ground(s) of rejection prompted by applicant's amendment to the claims. With respect to applicant's argument that Gilman does not teach a combination of a backing layer border portion with a first adhesive layer applied thereon only, to the exclusion of the remainder of film 12, Examiner has acknowledged this in the previous Office action, and reminds applicant that the rejection of claim 1 is under 35 U.S.C 103 for the specific reason that Gilman only teaches such an adhesive configuration on an opposite surface of film 12, but that it would be obvious to duplicate such a configuration by only adding adhesive to border portion 13a "so as to add additional integrity to the adhesion between backing layer 13 and base film 12".

Information Disclosure Statements

The information disclosure statements (IDS) submitted on April 5, 2006 and May 11, 2006 was filed after the mailing date of the Application on December 3, 2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-19 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gilman (U.S. Patent Application Publication No. 2003/0088202).

With respect to **Claim 1,3**: Gilman teaches wound dressing 10 having hydrophilic foam layer 11 (absorbent core) having two opposing body-side and backside surfaces, each having a central portion and a border portion, a liquid-impermeable and vapor-permeable backing layer 13 defining opposing proximal and distal surfaces extending over a distal surface of foam 11 having a border portion 13a that overlies foam layer 11 and extends beyond the periphery of foam layer 11. The distal surface of backing layer 13 defines the backside of said dressing. Adhesive layer 16 is disposed on the entirety of the bodyside surface of base film 12, including that attaches border portion 12a of base film 12 and border portion 13a to one another. ('202, ¶¶ 0015, 0016) Gilman only explicitly teaches that adhesive layer 16 is present in border portion 12a, however since Gilman also teaches that backing layer 13 is not attached to the foam layer 11 by any adhesive means, it would be obvious to one of ordinary skill in the art to add adhesive only to the border portion 13a so as to add additional integrity to the adhesion between backing layer 13 and base film 12.

With respect to **Claim 2,14**: As can best be seen in Figs. 1 and 2, border portion 13a is parallel to the proximal surface of layer 11.

With respect to **Claim 4,15**: As can best be seen in Fig. 1, border portion 13a is defined by at least two opposing elongate sections extending from a corresponding side of foam layer 11 (absorbent core).

With respect to **Claims 5,6,16**: Gilman teaches that the adhesive in adhesive layer 16 (which is intended to contact the skin) is a suitable hypoallergenic pressure sensitive adhesive, specifically a hydrogel adhesive, which is an elastomeric adhesive. ('202, ¶¶ 0015, 0017)

With respect to **Claim 17**: Gilman teaches that backing layer 13 does not contain adhesive in the area overlying foam layer 11 *in a preferred embodiment*. ('202, ¶ 0016) Examiner asserts that Gilman is thus implicitly teaching that backing 13 is capable of carrying a layer of adhesive 16 in the area overlying foam layer 11 that extends along the entire proximal surface of backing layer 13.

With respect to **Claim 8,18**: Gilman teaches that adhesive layer 16 is sufficiently porous as to be vapor-permeable. ('202, ¶ 0015).

With respect to **Claim 9**: Gilman does not teach a second skin adherent facing layer secured to the proximal surface of foam layer 11, however Gilman teaches delivery assisting layer 20 defining a plurality of apertures 21 arranged in a pattern forming a surface opposite the skin-adhering surface, having finger gripping tabs for purposes of holding and applying the dressing. It is well known in the art to provide a second release, or delivery assisting sheet on a skin-adhering surface of a wound dressing or bandage to prevent contamination of the absorbent portion intended for placement adjacent a wound during packaging and transport, therefore it would be obvious to one of ordinary skill in the art to provide a second skin adherent facing layer to the dressing taught by Gilman that is identical to layer 20, i.e. having adhesive so as to also be skin-adherent, said second skin adherent facing layer defining a plurality of apertures as taught by Gilman and forming a portion of the bodyside surface.

With respect to **Claim 10,19**: Gilman teaches that adhesive 16 is used both to attach the bodyside surface of base film 12 to the skin of the user and to attach the border portions 12a and 13a to each other. Given this structure and the purpose of the dressing, Examiner asserts that the amount of adhesive applied to secure the border portions 12a to 13a has to be greater than in layer 16 on base film 12 even though the surface area of adhesion is less than that of the area of adhesion between the base film and the skin so as to ensure that backing layer 13 does not "pop up" or dislocate from the foam layer 11 upon activation of the pressure sensitive adhesive occurring when dressing 10 is pressed against the skin.

With respect to **Claim 11**: Gilman teaches delivery assisting layer 20 that is weakly attached to backing layer 13, thus being dissociated from the distal surface of foam layer 11 and extends over an intermediate portion of foam layer 11 that is between a central portion and a border portion of said foam layer.

With respect to **Claim 12**: Please see the rejections of Claims 1 and 9 as these rejections collectively address all of the limitations of claim 12.

With respect to **Claims 21-23**: Gilman teaches wound dressing 10 having hydrophilic foam layer 11 having two opposing surfaces, each having a central portion and a border portion, a liquid-impermeable and vapor-permeable backing layer 13 adjacent a distal surface of foam 11 having a border portion 13a that overlies foam layer 11 and extends beyond the periphery of foam layer 11, and adhesive layer 16 disposed on the entirety of the bodyside surface of base film 12, including that attaches border portion 12a of base film 12 and border portion 13a to one

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another. ('202, ¶¶ 0015, 0016) Gilman only explicitly teaches that adhesive layer 16 is present in border portion 12a, however since Gilman also teaches that backing layer 13 is not attached to the foam layer 11 by any adhesive means, it would be obvious to one of ordinary skill in the art to add adhesive only to the border portion 13a so as to add additional integrity to the adhesion between backing layer 13 and base film 12. Gilman teaches that the adhesive in adhesive layer 16 (which is intended to contact the skin) is a suitable hypoallergenic pressure sensitive adhesive, specifically a hydrogel adhesive, which is an elastomeric adhesive. ('202, ¶¶ 0015, 0017) Gilman does not teach a second skin adherent facing layer secured to the proximal surface of foam layer 11, however Gilman teaches delivery assisting layer 20 defining a plurality of apertures 21 arranged in a pattern forming a surface opposite the skin-adhering surface, having finger gripping tabs for purposes of holding and applying the dressing. ('202, ¶¶ 0020, 0021) It is well known in the art to provide a second release, or delivery assisting sheet on a skin-adhering surface of a wound dressing or bandage to prevent contamination of the absorbent portion intended for placement adjacent a wound during packaging and transport, therefore it would be obvious to one of ordinary skill in the art to provide a second skin adherent facing layer to the dressing taught by Gilman that is identical to layer 20, i.e. having adhesive so as to also be skin-adherent, said second skin adherent facing layer defining a plurality of apertures as taught by Gilman and forming a portion of the bodyside surface.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilman ('202) in view of Samuelsen (U.S. Patent No. 4,867,748).

With respect to **Claim 20**: Gilman does not teach that foam layer 11 is beveled. Samuelsen teaches a wound dressing wherein an absorbent layer is beveled downwardly and inwardly

towards a central axis from a distal surface with respect to a backing layer to a proximal surface. Samuelsen teaches that beveling the absorbent allows the thinner portion of said absorbent in the beveled region to stop the flow of adhesive plasticized due to heating from contact with the skin from seeping out from the edge of the cover layer and damaging bed linens or other fabrics and thus eliminating the need for the placement of tape around the periphery of the bandage, ('748, Col. 2, lines 40-50), therefore it would be obvious to one of ordinary skill in the art to bevel the foam layer 11 of the dressing taught by Gilman in the manner taught by Samuelsen.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

MJH

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

